

Three adult ( $\geq 18$  years) cohorts from The Epidemiology and Natural History of Asthma: Outcomes and Treatment Regimens (TENOR) 3-year observational study were defined: patients on SFC Low-Dose (100/50 or 250/50  $\mu\text{g}$ ), patients on SFC High-Dose (500/50  $\mu\text{g}$ ), and patients on other medications (including salmeterol and fluticasone), but not on SFC. Using standard regression methods, we computed unadjusted and propensity score adjusted differences in 24 month outcomes between the treatment cohorts. **RESULTS:** After adjustment for confounding, the Low-Dose SFC cohort had higher asthma-related quality of life ( $P = 0.0026$ ), fewer asthma control problems ( $P = 0.0001$ ), similar rates of exacerbations ( $P = 0.8932$ ), marginally higher FEV1 ( $P = 0.0777$ ) and lower odds of having severe asthma ( $P = 0.0454$ ) compared with controls (patients never on SFC). After adjustment for confounding, the High-Dose SFC cohort had no difference in asthma-related quality of life, asthma control problems, or exacerbation rates ( $P = 0.1879, 0.3015, 0.3560$  respectively), higher FEV1 ( $P = 0.0011$ ), and higher odds of having severe asthma ( $P = 0.0137$ ). **CONCLUSIONS:** The results support evidence that some asthmatics achieve better control while taking low-dose SFC, but also suggest that high-dose SFC fails to provide clinically significant benefit in terms of most asthma-related health outcomes when compared to similar patients not taking high-dose SFC. These findings may highlight an unmet need in severe or difficult-to-treat asthma and call for alternative therapeutic approaches in those unable to attain asthma control with or without SFC.

## PAA2

#### EXACERBATION RATES FOR SINGLE VS. DUAL CONTROLLER THERAPY FOR MILD-PERSISTENT ASTHMA

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**OBJECTIVES:** Asthma exacerbation rates in a large Midwest health plan were compared for single and dual controllers. **METHODS:** The asthma cohort included 788 patients prescribed at least 1 SABA and 2 controller prescriptions during a 6 month intake period, with mild persistent severity defined by rates of ED or hospital admission, SABA and OCS fills. Patients older than age 55, diagnosed with COPD or prescribed more than one type of controller were excluded. Exacerbations were defined by Kaplan-Meier, as time to asthma-related hospital or ED admission. Significance was further tested using Cox proportional hazards stratified by age, gender, control, severity, and adherence during a six-month pre-index period. **RESULTS:** Leukotriene modifiers (LM) were prescribed as a single controller for 38% of patients, inhaled corticosteroid (ICS) for 27%, and dual controller (DC, fluticasone/salmeterol) for 36%. DC were prescribed most often in older adults (55%), while LM were most often prescribed in children (62%). Asthma severity as defined by the number of SABA and OCS fills and exacerbations in the intake period was similar for the three cohorts. Asthma control ( $>4\times$  controller/SABA) was highest for LM (89%). Controller adherence rates were lowest in the ICS cohort with 76% filling  $<4$  prescriptions compared to 53% for DC and 44% for LM. Two-year exacerbation rates were 19% for ICS, 20% for LM and 18% for DC ( $P = 0.99$ ). In the multivariate model, older adults less likely suffered exacerbations compared to children (hazard ratio = 0.63, 95% CI 0.44–0.91,  $P = 0.013$ ). **CONCLUSION:** An algorithm was developed to identify patients with mild-persistent asthma in administrative claims. Multivariate models were constructed to control for demographics, asthma severity, control and adherence rates. Kaplan-Meier statistics indicates exacerbation rates were highest among children, but were similar in patients receiving LM, ICS or DC.

#### EVALUATION OF RISK FACTORS AND PREDICTORS OF HEALTH OUTCOMES AMONG PERSONS WITH ASTHMA

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**OBJECTIVES:** To examine risk factors associated with health care utilization in Arizona Medicaid patients with asthma. **METHODS:** Data were obtained from Arizona Medicaid between 1/1/2002 and 12/31/2003. Inclusion criteria consisted of persons with an asthma diagnosis (ICD9-CM 493.xx), 5–62 years of age; and were new users of inhaled-corticosteroids (ICS), combination ICS+long-acting beta-agonist, or leukotriene-modifiers. Factors examined included age, geographic location (urban/rural), race/ethnicity (White, non-Hispanic Black, Hispanic, other), medication adherence, pre-period short-acting beta-agonist use (SABA), and co-morbidities. Utilization measures examined included post-period SABA use, exacerbations measured by emergency-room or hospital visits, asthma-related and total health care costs. Analyses for utilization measures were performed using negative binomial, logistic regression, and generalized linear modeling gamma-family, log-link, respectively. **RESULTS:** A total of 3013 subjects met inclusion/exclusion criteria and had a mean age ( $\pm$ SD) of 24.7  $\pm$  13.7 years. Urban residents were 54% more likely to have an exacerbation than rural residents (odds ratio-OR 0.46, 95%CI: 0.30–0.79). Age (years 18–39) was a significant predictor across all analyses: SABA use (incidence rate ratio-IRR 1.24, 95%CI: 1.06–1.44); exacerbations (OR 2.22, 95%CI: 1.34–3.68); mean asthma cost (\$702.47, 95%CI: \$600.07–822.34); mean total health care cost (\$5445.67, 95%CI: \$4852.18–6111.76). Age (years 40–62) significantly predicted mean total health care cost: \$5662.88, 95%CI: \$4814.67–6660.53. Males were 47% less likely to have an exacerbation than females (OR 0.53, 95%CI: 0.30–0.91). Exacerbations were not different between race/ethnicity categories. Predicted mean asthma-related costs were not different between Whites (\$590.65, 95%CI: 508.80–565.68), Blacks (637.68, 95%CI: 499.10–814.75), or Hispanics (534.79, 95%CI: 466.14–613.55). **CONCLUSION:** Results of these analyses found urban areas had higher rates of asthma-related hospital visits compared to rural counties, but no significant difference in asthma-costs between urban and rural areas. Persons with asthma aged 18–39 had higher rates of asthma-related emergency-room visits/hospitalizations and costs than those aged 5–17 and 40–62. Race/ethnicity was not a significant predictor of outcomes or asthma-related costs.

## PAA4

#### ADVERSE DRUG REACTIONS IN ECONOMIC EVALUATIONS

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**OBJECTIVES:** To review the health economic literature for drugs that have since been withdrawn for safety reasons. To assess the cost-effectiveness of the non-sedating anti-histamine, terfenadine (withdrawn in 1998 for its cardiotoxicity) compared with chlorpheniramine, a sedating anti-histamine which is still available. **METHODS:** Literature searches of economic evaluations of drug that have been withdrawn since 1980 were conducted. A decision analysis comparing terfenadine with chlorpheniramine was developed. Observational data were obtained for estimates of the incidence of ventricular dysrhythmias, the incidence of serious injuries as a consequence of sedation with chlorpheniramine, and the risk of death resulting from arrhythmias or serious injuries. Health state utilities and data on